DATE: October 23, 2025

TO: Hearing Attendees and Commenters –
Oregon Administrative Rules chapter 333, divisions 76 and 77 –
"Freestanding Birthing Center Licensure Requirements"

FROM: Brittany Hall, Hearing Officer and Administrative Rules Coordinator

cc: Dana Selover, Section Manager
Health Care Regulation and Quality Improvement

SUBJECT: Presiding Hearing Officer's Report on Rulemaking Hearing and Public Comment Period

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Hearing Officer Report

Date of Hearing: January 17, 2025, via Microsoft Teams

Purpose of Hearing: The purpose of this hearing was to receive testimony regarding the Oregon Health Authority (OHA), Public Health Division, Health Care Regulation and Quality Improvement (HCRQI) program's proposed permanent adoption of administrative rules in chapter 333, division 077, and repeal of administrative rules, amendment and renumbering of administrative rules in chapter 333, division 076 relating to the licensing requirements for freestanding birthing centers.

In accordance with ORS chapter 441, the OHA is responsible to ensure a safe and healthy environment is provided by over 800 health-related facilities and agencies. The OHA is required to license and conduct on-site inspections of these facilities which include freestanding birthing centers. The freestanding birthing center rules were last revised in 2006 and the OHA is amending the rules to align with modern clinical practice. The rules have been renumbered and assigned their own division number for clarity.

The following changes have been made:

- Added and amended definitions;
- Updated licensing processes to align language with other licensed health care facilities for better clarity including clarifying the review and approval process for a license application; identifying governing body responsibilities; personnel requirements; allowing for waivers; clarifying the complaint, investigation, survey, and enforcement process.
- Updated required policies and procedures.
- Added new emergency preparedness requirements based on consideration of new federal regulations for other health care facility types.
- Revised construction standards.
- Identified requirements for admission, discharge, client care, and client services.
- Amended risk status assessment requirements and added consultation requirements for certain risk factors. Risk factor tables were amended based on separate, although similar, standards adopted by the OHA, Health Licensing Office (Board of Direct Entry Midwifery) as well as the Health Evidence Review Commission.
- Non-substantive edits were made to ensure consistent terminology throughout HCRQI rules and policies, made general updates consistent with OHA practices, updated statutory and rule references, corrected formatting and punctuation, and made changes to improve the accuracy, structure and clarity of the rules.

Hearing Officer: Brittany Hall

Testimony Received: Three individuals provided testimony at the hearing.

Other Comments: Eight individuals or organizations submitted written comments to OHA within the period allotted for public comment, which closed at 5:00 PM on March 17, 2025. Written comments are attached to this report as **EXHIBIT 1**.

In oral testimony OHA heard a concern about the lack of diversity and representation of marginalized communities on the Rule Advisory Committee and in the public meetings held related to this rulemaking.

Agency response: In May 2019, the Birthing Center Rule Advisory Committee (RAC) was formed to gather input from those affected by proposed rules in accordance with the Administrative Procedures Act (APA). Initial RAC members included:

- A selection of licensed freestanding birthing center administrators
- Oregon Midwifery Council
- American Association of Birth Centers
- Oregon Association of Birth Centers
- Oregon Association of Hospital and Health Systems
- Oregon Association of Naturopathic Physicians
- Oregon Affiliate of the American College of Nurse Midwives
- Oregon State Board of Nursing
- Consumer
- Providers including a licensed physician specializing in neonatology

Following the implementation of revisions to the APA in January 2022 that required inclusion of impacted communities, especially communities of color, two new members were identified to serve on the RAC:

- Forward Together, Birth Justice Committee
- OB/GYN hospitalist

Since most of the RAC's rule revisions were completed by the date of implementation of changes to the rulemaking process, OHA, Public Health Division decided to get additional community feedback by hosting a community meeting seeking input from the community on the completed proposed rule changes. HCRQI staff conducted the meeting after a broad recruitment among organizations and groups representing communities of color as required by the expanded law.

Lastly, the public comment period ran for 82 days following a request to extend the public comment period (December 26, 2025 through March 17, 2025). Notices were sent to over 9,300 subscribers across birthing center and hospital listservs, RAC members, licensed midwives, coordinated care organizations, licensed freestanding birthing centers, professional and trade associations, relevant architects, and community organizations.

In oral testimony and written comments about the increased costs that the rule changes will have on freestanding birthing facilities, a question was asked about what OHA's plan is to work with the Oregon Health Plan and private Medicaid plans to increase reimbursement to cover the increased costs and fiscal impact associated with these changes. Written comments expressed concern that the proposed rule changes will have a negative effect on racial health equity in the State of Oregon stating that they will

restrict access to birthing care and violate a birthing person's right to make their own health care decisions.

Agency response: The OHA has a multifaceted role in developing regulations for and supporting safe, accessible out-of-hospital births through the following Divisions:

- **Medicaid Division** Provides guidance for prior authorization process and billing for planned out-of-hospital births under the Oregon Health Plan (OHP). This ensures midwives and birth centers are reimbursed for services while maintaining safety standards.
- **Public Health Division (PHD)** Monitors maternal and infant health outcomes, supports data collection, and promotes best practices for out-of-hospital birth providers. Additionally, the PHD is responsible for adopting administrative rules for freestanding birthing centers, licensed for the primary purpose of performing low-risk deliveries. These rules must include, but are not limited to, standards for patient care and safety. PHD also oversees licensing and compliance for midwives and other birth professionals, ensuring they meet state standards for safe practice
- **Health Policy and Analytics Division** operates the Health Evidence Review Commission (HERC) to ensure that certain medical procedures, devices and tests paid for with Medicaid healthcare funds are safe and proven to work. HERC revised their Coverage Guidance for planned out-of-hospital birth in 2020.

Implementing regulations for out-of-hospital births requires a thoughtful balance between safeguarding the well-being of clients, respecting a client's autonomy, and promoting health equity across diverse populations. Regulations must ensure that care environments are safe for freestanding birthing centers that perform low-risk deliveries. Regulations must also consider the varying scopes of practice of providers providing services in a freestanding birthing center, while also honoring the right of individuals to choose how, where, and by whom their care is delivered. Similar to the difference between ambulatory surgery centers and hospitals, regulations for patient care in freestanding birthing centers and hospitals will require risk assessment to account for patient acuity and facility capability to provide the right care at the right time in the right place.

In oral testimony OHA heard a request for clarity around who can own a birth center. Comments specifically questioned if a traditional midwife or non-licensed provider can

own 51 percent or more of a birth center, or whether 51 percent or more ownership has to be by a licensed certified professional midwife (CPM) or other birth provider.

Agency response: There is nothing in the rules that limits who is eligible to own a freestanding birthing center. Under OAR 333-077-0070(3)(f), the rules limit the "supervision of client care and services" to a licensed direct entry midwife, certified nurse midwife, or physician. This means an owner who is a certified professional midwife (CPM) may not supervise the clinical care and services provided to a client by a direct entry midwife, certified nurse midwife, or physician.

In oral testimony and written comments OHA heard concern about the increased costs that will result from the changes related to food service and storage. Written comments stated concern that for birth centers located in rural communities, the requirement that food be prepared in a certified restaurant kitchen is not feasible. Written comments also noted that the requirement for only single service utensils or food packaging to be used is not sustainable financially or environmentally, will be cost prohibitive for birth centers, and will detract from the efficacy, nutritional quality, and customization of each meal that is served. Written comments also noted that it is not culturally appropriate for all birth center clients to be served prepackaged meals or to be required to eat from single use utensils, as many birthing people follow a specialized meal plan after giving birth that excludes food in direct contact with plastic. They noted that a birth center is a home-like setting different from a hospital and stainless-steel silverware should be acceptable. Alternatively, it was proposed that birth centers continue to be able to prepare and serve food and that all staff be required to obtain and maintain a food-handler's card.

Agency response: The OHA, Public Health Division has considered the comments provided and has consulted with the Oregon Health Authority, Foodborne Illness Prevention Program. OAR 333-077-0160 and OAR 333-077-0220 have been amended as follows:

333-077-0160 Dietary Services
(1) As used in this rule, "potentially hazardous food" means any food or beverage that contains milk or dairy ~~milk~~ products, eggs, meat, fish, shellfish, poultry, cooked rice or beans, raw seed sprouts, cut melons, cut leafy greens, heat-treated vegetables and vegetable products, and all other previously cooked foods.

(2) A birthing center shall make dietary services available to provide clients and family members with nutritious liquids, snacks, or other foods.
(3) A birthing center must be able to store, refrigerate, and reheat food to meet the needs of a client.
(a) Food shall be stored in a space used only for food, beverages, and kitchen ~~single-service~~ utensils;
(b) Any food or beverage brought to the birthing center by the client or a client's family member shall be 'ready to eat' and labeled with the client's name and dated. 'Ready to eat' food shall not include raw meat and must be discarded promptly after the client is discharged from the birthing center.
(c) All food must be discarded after service from the kitchen to the client.
(d) Any food prepared or assembled for a client after admission to the birthing center must be promptly discarded if the food has not been consumed within 24 hours or is leftover after the client is discharged from the birthing center.
(4) Prior to the preparation, assembly or handling of food that will be eaten by a client or a client's family member, birthing center staff must complete a food handler training program and obtain a certificate of program completion from the Oregon Health Authority, local public health authority, or a designated agent.
(5~~b~~) At least one refrigerator~~, in good operating condition,~~ shall be on-site that is adequate to store all potentially hazardous foods at or below 41 degrees Fahrenheit.
(a~~A~~) A thermometer in working condition shall be affixed to the door, or the front edge of the top shelf, of each refrigerator. ~~(B)~~ Refrigerators equipped with a temperature gauge visible from the exterior are acceptable.
(b) A refrigerator used for food storage shall have a sign or label identifying the refrigerator is for food storage only.
~~(c) Any food or beverage brought to the birthing center by the client or a client's family member shall be 'ready to eat' and labeled with the client's name and dated.~~
~~(d) All food or beverage products served by the birthing center shall be commercially-prepared, individually-packaged, single-serving foods.~~
~~(e) All food, once removed from the kitchen for service, shall be discarded.~~
~~(f) Leftover prepared food which has not been served shall be labeled and dated, rapidly cooled, and used within 36 hours.~~
(6~~4~~) A birthing center may make arrangements with an external vendor to prepare or deliver food to the birthing center. All catered or delivered foods shall be:
(a) Prepared by a licensed food establishment or in a kitchen approved by the Oregon Health Authority or local public health authority; and
(b) Delivered in a safe, sanitary manner with food maintained at the required temperature specified in this rule.

(~~7~~5) All potentially hazardous food shall be kept at 41 degrees Fahrenheit or below, or 135 degrees Fahrenheit or above. ~~(a)~~ Foods requiring refrigeration after preparation shall be uncovered or put in a shallow pan and placed in a refrigerator ~~rapidly cooled to a temperature of~~ at 41 degrees Fahrenheit or below.
~~(b) Refrigerated storage space at 41 degrees Fahrenheit or less shall be used to store meals which contain potentially hazardous food.~~
~~(c) Foods that have been cooked, and then refrigerated, shall be reheated rapidly to at least 165 degrees F before being served or placed in a hot food storage unit.~~
(~~8~~6) Eating utensils must be provided by the birthing center. Eating utensils must be washed, rinsed, and sanitized after each use in accordance with OAR 333-150-0000, chapter 4, parts 4-5, 4-6, and 4-7. Alternatively, the birthing center may:
(a) Use ~~only~~ single service utensils ~~shall be used~~; or
(b) Provide a notice to clients stating, "For your convenience, dishes and utensils have been washed. If you would like to further sanitize these items, please contact staff." The sanitizing agent must be available where cleaning solutions are routinely stored.
(~~9~~7) All counters, shelves, tables, refrigeration equipment, sinks, drain boards, dish tables, cutting boards, appliances and other equipment used for food service shall be kept clean and in good repair.
(10~~8~~) Food contact surfaces and equipment shall be washed, rinsed and sanitized after each use in accordance with OAR 333-150-0000, chapter 4, parts 4-5, 4-6, and 4-7.
~~(9) A birthing center that provides food services prepared on-site and to the public shall meet the requirements of the Food Sanitation Rules, OAR 333-150-0000.~~
(11) The administrative rules specified in sections (8) and (10) of this rule can be found on the website: http://www.healthoregon.org/foodsafety.

OAR 333-077-0220 Physical Environment

….
(7) An applicant or a licensed birthing center must comply with the following requirements:
….
(e) Support areas for birthing center:
(A) An examination room is not required. If provided, the examination room shall provide adequate space to accommodate clients, support persons, and staff.
(i) For new construction or where seeking licensure of previously unlicensed space, a handwash station is required in the examination room. Handwash station shall include soap and single use paper or cloth towels that are stored in a contactless enclosed dispenser to prevent contamination.
(ii) For renovation work within existing licensed space, a hand sanitation dispenser may be provided in the examination room in lieu of a handwash station.

(iii) Sharps disposal containers shall be provided in each examination room. If mounted to the wall, the top of sharps disposal container shall be placed no higher than five feet, zero inches vertical dimension above floor.
(B) Laundry service may be provided onsite or contracted. All laundry contaminated with bodily fluids shall be placed in bags in impervious receptacles.
(i) If laundry service is onsite, an area shall be provided that is large enough to accommodate the following:
(I) Washer/extractor(s). Washers/extractors shall provide a temperature of at least 160 degrees Fahrenheit for a minimum of 25 minutes or include use of a chemical disinfectant;
(II) Dryer;
(III) Storage shall be provided for laundry supplies. If laundry area is accessible to the public, all chemicals shall be secured within locked rooms or cabinetry; and
(IV) Separate and distinct areas shall be provided for processing soiled and clean laundry. A handwash station with soap and single use paper or cloth towels that are stored in a contactless enclosed dispenser to prevent contamination shall be provided within 20 feet of soiled linen area (measured along path of travel).
(ii) If laundry service is contracted, adequate storage of soiled laundry under staff control and protected from public access shall be provided.
(C) A kitchen shall be provided for staff, client, and support person use that includes:
(i) A sink with soap and single use paper or cloth towels that are stored in a contactless enclosed dispenser to prevent contamination. The handwash sink must remain accessible at all times and be free of dishes or food when used for handwashing.
(ii) A worksurface.
(iii) Means to hold food below 41 degrees Fahrenheit ~~keep food cold~~. Refrigerators for food cannot contain birth center medications, placentas, or laboratory specimens. The refrigerator shall have a sign or label identifying the refrigerator is for food storage only.
(iv) Means to heat food. Means for heating food shall be located or monitored to preclude tampering by children.
(v) Commercial-grade cooking equipment and appliances may be required by other authorities having jurisdiction.
(vi) Storage of dangerous or sharp utensils and equipment shall be secured to preclude access by children.
(vii) Toilet rooms cannot directly open to rooms where food is being prepared.
(viii) If ice is provided in the birthing center for therapeutic purposes or for consumption, it shall be self-dispensing to preclude possible contamination. Self-dispensing ice can be provided via refrigerator in-door dispenser or countertop ice dispenser as long as scoops are not used and hands cannot ~~easily~~ contact the ice.

(D) Medications and ancillary supplies:
(i) Medications, needles, and prescription pads shall be secure and lockable to preclude unauthorized use.
(ii) Sharps disposal containers shall be provided near the medical supplies. If mounted to the wall, the top of sharps disposal container shall be placed no higher than five feet, zero inches vertical dimension above floor.
(iii) If medication refrigerator(s) are included, they shall not store any food, placentas, or laboratory specimens. The refrigerator shall have a sign or label identifying the refrigerator is for medication only.
(iv) Medication refrigerators shall include a temperature gauge.
(v) A handwash station with soap and single use paper or cloth towels that are stored in a contactless enclosed dispenser to prevent contamination shall be provided within 20 feet of where medications are open
…

In oral testimony OHA heard the request for a 60 to 90-day grace period for license renewals that are due by December 31, and a request for the OHA to inform a birth center via mail, email and phone if the OHA hasn't received their license renewal by mid-November. Without renewal by the December 31 deadline, facilities would be required to apply for a new license under updated licensing standards with which they are not otherwise required to comply. This may cause currently opened birth centers to close.

Agency response: Under ORS 441.015, operating a healthcare facility in Oregon without a valid license is prohibited. ORS 441.020 further requires that licensed healthcare facilities renew their licenses every year. As such, the OHA, Public Health Division cannot grant a 60 to 90-day grace period after the license expiration date, as that would permit the facility to operate without a license. To support timely renewal, the Public Health Division begins notifying licensed healthcare facilities, including freestanding birthing centers, in October of each year. These notifications outline the renewal process and deadline, effectively providing facilities a minimum of 60 days to complete their license renewal before the December 31 license expiration date. The Public Health Division also issues reminder emails and follow-up phone calls to facilities regarding license renewal. The rule will remain as currently proposed.

In oral testimony and written comments OHA heard concern about the changes to the risk criteria related to maternal mental illness requiring psychological or psychiatric

intervention. The rule changes will require pregnant people on psychotropic medications or in therapy to have an additional appointment with a hospital provider to be evaluated for safe delivery in a birth center. They noted that the added requirement for a consultation by a perinatal healthcare provider adds costs and inconveniences, and singles out birthing people with mental health concerns. It was also noted in written comments that mental health diagnoses, such as anxiety and depression, are very common in communities of color since they can be a natural outcome of living through systemic oppression and discrimination. Many people seek birth center care because they have found hospital-based care to be racially biased and traumatizing. Requiring that Black people and other people of color with these diagnoses work with a hospital system provider denies them the right to control their own care, right to consent, exacerbates trauma, and ultimately will result in worse birth outcomes for babies.

Agency response: The proposed administrative rules do not require that pregnant persons on psychotropic medications be evaluated by a *hospital* provider. Freestanding birthing centers are required to consult with a perinatal care provider if the client has a history of serious mood disorders that could affect the baby, has schizophrenia or similar psychiatric conditions, or develops psychiatric symptoms or conditions during pregnancy including taking psychotropic medications. The freestanding birthing center may consult with either a physician, certified nurse midwife, physician associate, nurse practitioner, or a licensed direct entry midwife. In making this decision, the Public Health Division considered its duty to ensure the safety and well-being of the client. The 2023, Oregon Maternal Mortality and Morbidity Review Committee Biennial Report noted that among pregnancy related deaths, nearly half of underlying causes of death were due to mental health issues or substance use disorders. The rule will remain as currently proposed.

In oral testimony it was questioned what the evidence and basis is to prohibit breach or twin delivery at a birth center, as well as what steps OHA is taking to ensure access to vaginal birth for breach and twin delivery in counties that otherwise have no access to this care.

Agency response: As previously noted, implementing regulations on out-of-hospital births requires a thoughtful balance between safeguarding the well-being of clients, respecting a client's autonomy, and promoting health equity across diverse populations. The OHA, Public Health Division is specifically responsible for safeguarding client health and safety. In its review, the Division considered regulations and guidance from the Medicaid Division, Health Policy and Analytics Division, and the Health Licensing

Office as well as current freestanding birthing center requirements. After careful consideration, the rule will remain as currently proposed, aligning with existing regulations. This upholds the existing requirement mandating the transfer of clients whose risk factors include breech presentation or multiple gestations to hospital-based care.

In oral testimony OHA heard a request related to the 48-hour requirement for authentication that verbiage be added about meeting the requirement "to the best of our ability" to allow for situations where something like a family emergency may occur immediately after birth and the authentication cannot happen within 48 hours as a condition of remaining a licensed birth center.

Agency response: The commenter likely refers to OAR 333-077-0130(4), which requires that "…entries in a client's labor record must be promptly dated, timed, and authenticated." The rule further allows labor record entries *after* 48 hours if marked as an addendum or amendment, with date, time, and provider initials. The current proposed rule already permits delayed documentation. The rule will remain as currently proposed.

In oral testimony and written comments OHA heard, in relation to the changes to risk criteria, concern that some of the changes will drive more birthing people to have unattended births or choosing to have a home birth when they can't give birth in a birth center, increasing risk when they are further from licensed facilities where they are close to back-up care. A request was made that there be more room for informed consent and autonomy in the risk criteria.

Agency response: As previously noted, implementing regulations for out-of-hospital births requires a thoughtful balance between safeguarding the well-being of clients, respecting a client's autonomy, and promoting health equity across diverse populations. Regulations must ensure that care environments are safe for freestanding birthing centers that perform low-risk deliveries. Regulations must also consider the varying scopes of practice of providers providing services in a freestanding birthing center, while also honoring the right of individuals to choose how, where, and by whom their care is delivered. Similar to the difference between ambulatory surgery centers and hospitals, regulations for patient care in freestanding birthing centers and hospitals will require risk assessment to account for patient acuity and facility capability to provide the right care at the right time in the right place. In considering the risk factors, the HCRQI section

enhanced flexibility for freestanding birthing center care by aligning with some of the regulations of the Board of Direct Entry Midwifery.

In written comments OHA heard the request for clear division of accountability between practitioner and birthing center as it relates to pharmaceutical services. It was noted that in many instances, it is unclear who might be responsible for certain elements within the continuum of care, or whether certain duties should be a responsibility of the licensee or would be more appropriately covered in the policies and procedures for the birthing center. Furthermore, it was noted that in some instances, a practitioner might be providing a service that is within their scope of primary licensure but may also require registration with other entities or professional licensing boards. It was also noted that it is unclear who is responsible for ensuring procurement standards for medications used in the birthing center, or what those standards might be, and standards relating to compounding practices.

Agency response: After review of the comments provided by the Oregon Board of Pharmacy and follow-up discussions with the Board's executive director, the OHA has amended OAR 333-077-0150 to clarify that accountability of pharmaceutical services lies with the clinical provider who has prescription-writing authority. The clinical provider with prescription-writing authority will be responsible for ensuring compliance with the Oregon Board of Pharmacy rules and regulations and determining whether the freestanding birthing center is subject to the requirements of registering as a Dispensing Practitioner's Drug Outlet. The rule has been amended as follows:

333-077-0150 - Pharmacy and Anesthetic Services
(1) In a birthing center, all medications must be prescribed, dispensed, or administered to a client within an individual clinical provider's license or scope of practice.
(2) The clinical provider shall be responsible for:
(a) Ensuring that a client receives the correct medication and the correct dosage.
(b) Ensuring that medication prescribed to a client is accurately labeled following the requirements of the Oregon Board of Pharmacy.
(c) Determining whether the pharmacy services provided under the clinical provider's license or scope of practice require that the birthing center be registered as a Dispensing Practitioner Drug Outlet with the Oregon Board of Pharmacy.
(d) Ensuring the birthing center system to inventory and monitor medications meets the requirements in section (3) of this rule and complies with any requirements established by the Oregon Board of Pharmacy.

(3~~1~~) A birthing center shall have a system to routinely inventory and monitor all prescription and non-prescription medications, intravenous fluids, and ancillary supplies. The system shall include, but is not limited to:
(a) Identification, storage, ~~and~~ security, and reconciliation of all medications, fluids and controlled substances; ~~that are deteriorated, outdated, misbranded, adulterated or otherwise unfit for use that are readily identifiable as defective and stored in a separate location from usable products; and~~
(b) Storage of deteriorated, outdated, misbranded, or contaminated medications or medications otherwise unfit for use be readily identified as defective and stored in a separate location; and
~~(b) Storage and security of medications including controlled substances that meet the requirements of the Oregon Board of Pharmacy in OAR chapter 855, division 41 and the U.S. Drug Enforcement Agency found in 21 CFR 1301.75(b).~~
~~(2) In a birthing center that does not have a pharmacy on the premises, stock quantities of prescription drugs, including local anesthetics, shall be stored on the premises only when such drugs have been obtained for dispensation or administration to respective clients by a clinical provider or other individual authorized within the scope of their professional license to dispense or administer such drugs. Prescribed drugs already prepared for clients in the birthing center may also be stored on the premises.~~
(c~~3~~) Proper disposal of expired medications, including special prescriptions for clients who have left the birthing center~~, shall be disposed of by incineration or other equally effective method, except controlled substances, which shall be handled in the manner prescribed by the U.S Drug Enforcement Administration under 21 CFR 1317 and the Oregon Board of Pharmacy under OAR 841-041-1046~~.
(4) Medications ~~Drugs~~ shall not be administered to a client~~s~~ unless ordered by a clinical provider or other individual authorized within the scope of their professional license to prescribe medications ~~drugs~~. Such orders shall be in writing and signed by the clinical provider or other authorized individual. An electronic signature or other authentication method is acceptable.
(5) Prescription medications ~~drugs~~ dispensed by a clinical provider or other individual authorized within the scope of their professional license shall be personally dispensed by the provider or other individual authorized within the scope of their professional license, unless otherwise authorized by rules of the Oregon Board of Pharmacy and the clinical provider's regulatory board. ~~Dispensing functions may be delegated to staff assistants when the accuracy and completeness of the prescription is verified by the clinical provider or other individual and where no independent judgement of the staff assistant is required.~~
~~(a) The dispensing clinical provider or individual shall label prescription drugs with the following information:~~

~~(A) Name of client;~~
~~(B) The name and address of the dispensing physician or nurse practitioner;~~
~~(C) Date of dispensing;~~
~~(D) The name of the drug. If the dispensed drug does not have a brand name, the prescription label shall indicate the generic name of the drug dispensed along with the name of the drug distributor or manufacturer, its quantity per unit, and the directions for its use stated in the prescription. However, if the drug is a compound, the quantity per unit need not be stated;~~
~~(E) Cautionary statements, if any, as required by law; and~~
~~(F) When applicable, an expiration date after which the client should not use the drug.~~
~~(b) Prescription drugs shall be dispensed in containers complying with OAR 855-043-0545.~~
(6) A birthing center shall maintain written prescriptions or orders, signed by a clinical provider or other individual legally authorized to prescribe, for all medications ~~drugs~~ administered to a client~~s~~ within the birthing center.
(7) All ~~medications, including~~ non-prescription medication ~~drugs~~ and nutritional supplements~~,~~ shall be clearly labeled with the client's name, ~~drug~~ name of medication, dosage, directions for use, and expiration date.
(8) General, spinal, caudal, or epidural anesthesia shall not be administered in the birthing center.
(9) Labor shall not be induced, stimulated, or augmented with any drug during the first or second stages of labor. Drugs may be administered within the individual clinical provider's scope of practice to inhibit labor, as a temporary measure, until referral or transfer of the client is complete.
(10) Nitrous oxide may be prescribed and dispensed in accordance with a clinical provider's scope of practice and in accordance with the following:
(a) A client must be assessed for suitability and absence of contraindications;
(b) Informed consent must be obtained from the client that clearly identifies potential risks;
(c) Clients must be educated in the use of the equipment and the nitrous shall be self-administered only. No assistance from birthing center staff or from other individuals is allowed;
(d) The nitrous oxide concentration must not exceed 50 percent and shall be administered through a scavenging system with a demand valve in a well-ventilated room;
(e) Clients self-administering nitrous oxide shall be continuously monitored for adverse effects by a trained clinical provider;
(f) Equipment shall be sterilized and stored in accordance with policies adopted pursuant to OAR 333-077-0090; and

(g) Staff shall be trained in the use of nitrous oxide in accordance with policies adopted pursuant to OAR 333-077-0090.

In written comments, possible conflicts with the American College of Nurse-Midwives and the Oregon Board of Licensed Direct Entry Midwives administrative rules relating to newborn care standards were raised. It was suggested that the OHA review established definitions in these rules and standards and consider whether additional clarification is needed for scope alignment.

Agency response: The purpose of OAR 333-077-0110(4)(b) is to ensure that freestanding birthing centers include information in the discharge plan about the newborn's necessary follow-up care. However, the rule does not specify who must provide that care; it remains the client's choice. The OHA acknowledges that, according to definitions from the American College of Nurse-Midwives and the Oregon Board of Licensed Direct Entry Midwifery, a "newborn" is considered to be 28 days old or younger, or one month or younger. Therefore, Certified Nurse Midwives and Licensed Direct Entry Midwives may not be authorized to conduct follow-up visits for infants aged 4 to 6 weeks. To clarify, the OHA has amended the rule as follows:

OAR 333-077-1110 Admission and Discharge
(4) A discharge plan shall be developed and communicated to the client and documented in the medical record.
(a) The discharge plan shall include, at a minimum, provisions for newborn screenings and follow-up care for both the client and newborn.
(b) The plan shall clarify that a newborn follow-up visit is necessary at two weeks and again between 6-8 weeks with a provider of the client's choosing, such as a pediatrician or other health care provider that is authorized within their scope of practice to provide follow-up care to a newborn.

A number of written comments were received regarding concerns about changes to Table I: Medical History or Obstetric History and Table II: Conditions of Current Pregnancy. These comments included:

- Recommendation that "retained placenta requiring surgical removal" be moved from Consultation Risk Criteria to Transfer Criteria. Written comments also recommended that in addition to molar pregnancy under "miscarriage/non-viable pregnancy," ectopic pregnancy be added as well.

- It was noted that the Oregon Health Evidence Review Commission (HERC) affirmed and reaffirmed that any type of vaginal birth after c-section was high risk. It was requested that OHA revise the administrative rules to remove high-risk vaginal birth after C-section (VBAC) from consultation and require transfer.
- Concerns were shared regarding Table I including objections to changes related to delivery history; Diabetes, Type 2; neurological disorders; and prior stillbirth/neonatal death. Table II concerns included objections to changes related to abnormal bleeding in pregnancy; amniotic fluid rupture – pre-labor rupture; hematologic conditions – Thrombocytopenia (platelets < 100,000); fetal growth; fetal presentation/multiple gestations; gestational age; hypertension; infectious conditions – Hepatitis B, Syphilis, Shingles; placental conditions; labor management – lack of adequate progress in 2nd stage with cephalic presentation; and perineal laceration – enlarging hematoma.

Agency response: The Public Health Division has considered the requested revisions to the risk factor tables, taking into consideration existing regulations for freestanding birthing centers and licensed Direct Entry Midwives, as well as the Commission for the Accreditation of Birthing Centers. In making these rule change decisions, the Public Health Division considered the balance between safeguarding the well-being of clients, respecting a client's autonomy, and promoting health equity across diverse populations. See the excerpts from Tables I and II below for change decisions. The risk factors and criteria have been modified to appear in alphabetical order. The Public Health Division further notes that while the administrative rule text under OAR 333-077-0120 clearly identifies that imminent fetal delivery may delay or preclude transfer before birth, this text has been added to Table II for further clarity.

OAR 333-077-0125 Risk Status Assessment and Consultation Requirements
TABLE I – Medical History or Obstetric History that Requires Transfer or Consultation

No change to the risk factor category, "delivery history and uterine conditions" – the rule will remain as currently proposed, with the exception of clarifying changes below.	
Delivery history and uterine conditions	• Absence of ultrasound to rule out placenta previa or placental placement to the surgical site • Conception occurred less than 12 months following surgery or uterine procedure • History of a known uterine perforation

	• History of cesarean section with ~~which included~~ classical incision • History of cesarean section with ~~and~~ complications including postoperative infection, diabetes, or steroid use • History of myomectomy which invaded the endometrium • History of two or more Cesareans sections without a prior successful vaginal delivery • Hysterotomy, other than cesarean • Uterine rupture
	• Prior myomectomy
No change to the risk factor category, "Diabetes mellitus" – the rule will remain as currently proposed.	
Diabetes mellitus	• Type 1 or Type 2; currently requiring oral medication or insulin
For the risk factor category, "Neurological disorders" – the Public Health Division agrees to remove this category from the table as it was not discussed during the Rule Advisory Committee meetings.	
~~Neurological disorders~~	~~• Neurological disorders or active seizure disorders that would impact maternal or neonatal health (e.g. epilepsy, myasthenia gravis, previous cerebrovascular accident)~~
For the risk factor category, "Fetal demise/prior stillbirth" – the Public Health Division agrees to add the reference "unexplained" as suggested and discussed in the RAC.	
Fetal demise/prior stillbirth	• Prior unexplained stillbirth/neonatal death
No changes to the risk factor category, "Placental conditions" – the rule will remain as currently proposed.	
Placental conditions	• Placenta accreta • Placenta increta • Placenta percreta
	• Retained placenta requiring surgical removal

TABLE II - Conditions of CURRENT PREGNANCY that Require Transfer or Consultation

For the risk factor category, "Abnormal bleeding in pregnancy" – the Public Health Division concurs with the suggestion to move 'antepartum hemorrhage, recurrent' from transfer to consultation and provided additional clarification.	
Abnormal bleeding in pregnancy	• ~~Antepartum hemorrhage, recurrent~~ • Hemorrhage (hypovolemia, shock, need for transfusion, vital sign instability)
	• Antepartum hemorrhage, recurrent in 2nd or 3rd trimester
For the risk factor category, "Amniotic membrane rupture" – the Public Health Division concurs with the suggestion to amend the consultation requirement for pre-labor rupture of membranes from greater than 24 hours to greater than 48 hours.	
Amniotic membrane rupture	• Before 36 weeks 0 days
	• Pre-labor rupture > ~~24~~ 48 hours
No changes to the risk factor category, "Fetal growth" – the rule will remain as currently proposed.	
Fetal growth	• Intrauterine growth restriction (IUGR) – fetal weight less than 5th percentile using ethnically-appropriate growth table, or concerning reduced growth velocity on ultrasound • Uteroplacental insufficiency
	• Inappropriate uterine growth (size-date discrepancy). An ultrasound read by a qualified physician constitutes a consultation.
No changes to the risk factor category, "Fetal presentation" – the rule will remain as currently proposed.	
Fetal presentation	• Breech • Non-cephalic
No changes to the risk factor category, "Gestational age" – the rule will remain as currently proposed.	
Gestational age	• Labor or premature rupture of membranes at <36 weeks 0 days • Pregnancy ≥42 weeks (unless already in active labor at 41 weeks 6 days)
	• Expected delivery date uncertain

No changes to the risk factor category, "Hematologic conditions" – the rule will remain as currently proposed.	
Hematologic conditions	• Hemoglobin < 8.5 g/dL at admission for labor • Thrombocytopenia (platelets < 100,000) • Thromboembolism, suspected or diagnosed • Thrombosis, suspected or diagnosed
No changes to the risk factor category, "Hypertensive disorders" – the rule will remain as currently proposed.	
Hypertensive disorders	• Eclampsia • Hypertension at or above 140 systolic or at or above 90 diastolic on two (2) separate occasions that are more than four (4) hours apart, or hypertension at or above 160 systolic or at or above 110 diastolic on one (1) occasion • Pre-eclampsia • Pre-existing or chronic hypertension
For the risk factor category, "Infectious conditions" – The Public Health Division concurs with removing reference to Shingles; active at labor. Hepatitis B positive status will remain as written. Unknown status of syphilis has been removed.	
Infectious conditions	• Diagnosed Chorioamnionitis • Genital herpes; primary outbreak at time of labor • Hepatitis B; positive status • HIV; positive status • Rubella; anytime during pregnancy • ~~Shingles; active at labor~~ • Syphilis; positive status ~~or unknown~~ • Varicella; active at labor • Maternal infection postpartum (e.g., endometritis, sepsis, wound) requiring hospital treatment • Two (2) temperatures at 100.4 degrees Fahrenheit or 38 degrees Celsius or greater within one (1) hour or one (1) temperature at 102.2 degrees Fahrenheit or 39 degrees Celsius or greater
	• CMV • Toxoplasmosis

For the risk factor category, "Labor management" – the Public Health Division concurs with adding a definition relating to adequate progress in 2nd stage with cephalic presentation and will align the definition with that used by the Board of Direct Entry Midwifery.	
Labor Management	• Induction; pharmacological • Lack of adequate progress in 2nd stage with cephalic presentation (no descent after a maximum of 3 hours of active pushing in cases with complete dilation and ruptured membranes)
For the risk factor, "Miscarriage/non-viable pregnancy" – the Public Health Division agrees with the recommendation to add a reference to ectopic pregnancy.	
Miscarriage/non-viable pregnancy	• Ectopic • Molar
No changes to the risk factor "Multiple gestation" – the rule will remain as currently proposed.	
Multiple gestations	• Multiple gestations
No changes to the risk factor category "Perineal laceration" – the rule will remain as currently proposed.	
Perineal laceration	• 3rd degree requiring hospital repair or beyond expertise of attendant • 4th degree • Enlarging hematoma
For the risk factor, "Placental conditions" – the Public Health Division concurs with the recommendation to amend the reference to include location of the placenta only. Other conditions will remain as listed.	
Placental conditions	• Abruption • Low lying with 2 cm or less of cervical os at ~~term~~ the last ultrasound prior to start of labor • Previa • Retained placenta > 60 minutes • Vasa previa

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In written comments it was requested that there be clear wording to allow birth centers to provide any services within their scope of practice whether or not OHA directly or indirectly regulates those services. Concern was noted specifically about OAR 333-077-

0025(4)(b) under "Approval of License Application" that OHA asserts that birth centers may not provide any services not already regulated by OHA through the clinics in birth center facilities. Written comments requested clarity as to whether OHA is viewing the "facility" as the same as the "clinic." There are services which OHA does not regulate, which may be beneficial, which should be continued to be offered as long as they are otherwise legal.

Agency response: Pursuant to ORS 441.025(12), a health care facility licensed by the OHA *may not offer or provide services beyond the scope of the license classification assigned by the OHA*, nor assume a descriptive title or represent itself under a descriptive title other than the classification assigned by the OHA. As such, the services provided in the freestanding birthing center are limited to those services defined in ORS chapters 441 and 442, and OAR chapter 333, division 077. If a clinical provider at the freestanding birthing center wishes to offer additional services but beyond what the freestanding birthing center license allows, those services must be clearly separate from freestanding birthing center services, take place in a distinct physical space not used for freestanding birthing center services or activities, and be documented in separate medical records from those of the freestanding birthing center. For example, a provider may use a designated room within the freestanding birthing center—one not used for freestanding birthing center services—to offer care within their professional scope. However, all aspects of that care, including records and space, must remain separate from the freestanding birthing center operations.

In written comments OHA heard objection to the requirement for a children's play area in OAR 333-077-0220, "Physical Environment," stating that the requirement should just be for an adequate waiting area.

Agency response: The OHA, Public Health Division is amendable to removing the requirement that the reception and waiting area of a freestanding birthing center must include a play area for children. It should be noted that this language was added based on the RAC's recommendation that the physical environment standards align with the Commission for the Accreditation of Birth Centers which requires a play area. The rule has been amended as follows:

OAR 333-077-0220 Physical Environment
(7) An applicant or a licensed birthing center must comply with the following requirements:
…

(f) Support areas for visitors:
(B) A reception and waiting area shall be provided~~, including a play area for children~~.

Lastly, the Public Health Division notes that references to the Oregon Structural Specialty Code (OSSC) in OAR 333-077-0220 have been modified to reference the 2025 version given the length of time that has passed since the RAC was first convened in 2019. The OSSC was modified in 2022 and again in October 2025. Application of the OSSC and the revised physical environment rule are not retroactive and will apply only to new construction or major alteration as applicable.

EXHIBIT 1

From: Arika Bridgeman
To: Public Health Rules
Subject: Public Comment on Birth Center Rules
Date: Monday, March 17, 2025 12:21:44 PM

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Hi,

I am writing to provide public comment on the proposed rules for freestanding birth centers. I've conducted research about Black birth prematurity and low birth, and interviewed Black midwives across the country. I'm also on a founding board which is seeking to establish a Black Birthing Village in Portland.

I'm deeply concerned about the implications of some of the proposed rules and am writing to testify against them. The two main concerns I have are with the requirement that birthing parents with a mental health diagnosis would need to consult with a hospital provider. Mental health diagnoses such as anxiety and depression are very common in communities of color since they can be a natural outcome of living through the systemic oppression and discrimination we do on a daily basis. Many people seek birth center care because they have found hospital-based care to racially biased and traumatizing and health data bares this out. Requiring that Black and other folks of color with these diagnoses work with a hospital system provider denies them the right to control their own care, right to consent, exacerbates trauma, and ultimately will result in worse birth outcomes for babies. Please do not implement this rule!

Second, I would like to contest the requirement for disposable kitchen utensil, pots pans etc. This is not sustainable financially or environmentally, it will be very cost prohibitive for birth centers, and birth centers and birth centers frequently use pots, pans etc. to prepare items that are relevant to the birth. This increase in cost would also make it very hard for birth centers to be viable.

Thank you for hearing my concern,

--
Arika Bridgeman-Bunyoli, MPH
Independent Consultant

From: hunte roberta
To: Public Health Rules
Subject: Public comment on Birth Center Rules
Date: Monday, March 17, 2025 4:20:28 PM

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Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Hello -
I am writing to provide public comment on the proposed rules for freestanding birth centers. I'm a maternal health researcher at PSU focused on maternal health disparities and community based intervention. I'm also leading a collective called Black Futures for Perinatal Health which is seeking to establish a Black Birthing Village in Portland.

I'm deeply concerned about some of the proposed rules and do not support them. The two main concerns I have are with the requirement that birthing parents with a mental health diagnosis would need to consult with a hospital provider. Mental health diagnoses such as anxiety and depression are very common in communities of color and are responses to racism-related stress, high ACES scores, and social determinates of health precarity. We do not have an abundance of mental health providers in our community. I support working with people around their mental health. I do not support this being a barrier to accessing birth center care. Forcing people to engage with a hospitalist around this is not trauma informed or helpful to all concerned. It will increase anxiety as it removes the agency from the birthing person to identify the care that is most supportive of their needs. Please do not move forward with this rule.

Second, I do not support the requirement for disposable kitchen utensil, pots pans etc. This is not sustainable financially or environmentally. This adds an undo burden to birth centers.
Thank you,
Regards,
Roberta Suzette Hunte, Phd

Oregon Association
— OF BIRTH CENTERS —

To Mellony Bernal, Dana Selover and the Oregon Health Authority,

March 17, 2025

Re:

The Oregon Association of Birth Centers (OABC) respectfully submits the comments below in response to the Oregon Health Authority's (OHA's) proposed revisions to the administrative rules in chapter 333, division 076, *new* division 077, relating to the licensing requirements for freestanding birth centers (FBCs), including OHA's Notice of Proposed Rulemaking Including Statement of Need & Fiscal Impact filed on 12/24/2024 in relation to the proposed regulations. OABC is a non-profit membership organization that promotes and supports Oregon freestanding birth centers in improving the health and lives of the people who seek care at freestanding birth centers. OABC advocates for policies that improve access to FBC services, reduce discriminatory or medically unjustified barriers to access, eliminate discriminatory barriers to coverage for FBC services, and expand available services and providers for underserved populations.

I. OABC's Participation in the Rulemaking Advisory Committee

OABC's attorney representative, Hermine Hayes-Klein, JD, participated on the Rulemaking Advisory Committee for the proposed rules, consistently attending dozens of RAC meetings that were held over five years, from May 30, 2019 to June 4, 2024. OHA's Statement of Need and Fiscal Impact for the proposed rules incorrectly states that OABC "described themselves as representing all Oregon licensed freestanding birth centers." In fact, OABC was clear at the RAC meetings that the organization represents all of its member freestanding birth centers, who comprise most, but not all, licensed FBCs in Oregon (currently, 11 out of 13). OABC was uniquely positioned on the RAC to assess the practical and fiscal implications f the proposed rules, and to communicate feedback to OHA on the impact of proposed amendments in the context of the urban, suburban, and rural communities around the State.

II. Comments on Statement of Need & Fiscal Impact

Before commenting on specific proposed regulatory amendments that will predictably restrict access to FBCs, OABC offers these comments on the Statement of Need and Fiscal Impact that OHA has filed to justify the proposed amendments.

a. The Proposed Rules Restrict Access Without Justification

As OHA acknowledges in its Fiscal and Economic Impact Statement, the new rules will increase the costs to FBCs of providing those services, which will foreseeably restrict access to those services by increasing the costs of those services to the public. The proposed rules will also restrict access to FBC services by reducing FBCs' scope of practice, forcing FBCs to turn away pregnant patients who are otherwise within midwives' scope of practice and entitled to midwifery care. For example, the current rules allow FBCs to provide care to clients whose pregnancies go past 42 weeks, so long as non-stress tests indicate that the pregnancy remains healthy. The new rules would require FBCs to refuse care to any pregnant woman whose pregnancy goes past 42 weeks, regardless of the health of her pregnancy and her own informed decision about what is best for her in the circumstances.

Any clinical decision that OHA mandates through Table I – III of the proposed rules takes away the pregnant patient's right, guaranteed by ORS 127.507 among other authorities, to make their own medical decisions in a private dialogue with their licensed provider. The proposed regulations requiring transfer of care would not allow FBCs to provide ethical care because they mandate abandonment of patients who decline the recommendation to present at a hospital for care. OABC presented evidence at early RAC meetings that countries with well-integrated community birth options, like the United Kingdom and the Netherlands, protect patients' rights and midwives' ability to honor their ethical duty of non-abandonment, by requiring midwives to continue care if a client declines a recommendation to transfer. At no time over five years of RAC meetings has OHA presented evidence or argumentation to justify regulating in detail the decisions that pregnant patients make with their providers in the FBC setting. OHA does not micromanage clinical decision-making between pregnant patients and their providers in its regulation of hospitals or obstetric clinics.

At almost every meeting of the RAC, OABC and the representatives of licensed FBCs on the committee asked OHA to provide any evidence that proposed restrictions on access to FBC services were based on medical evidence that the proposals would actually improve health outcomes for pregnant people or babies, or any evidence that the scope of practice under the existing rules had resulted in negative outcomes or safety gaps that justify the restrictions. At no time was any such evidence produced or presented to the RAC. OHA has never identified any evidence that any proposed restriction on access to FBCs in Oregon is medically justified, will improve outcomes, or will reduce preventable harm.

The *only* medical evidence cited in the Statement of Need and Fiscal Impact related to birth center access, CMS' Strong Start Initiative, demonstrated that access to FBCs results in better outcomes for mothers and newborns—including reduced risks of preterm birth, low birth weight, and cesarean section—at lower costs for healthcare payers. This evidence justifies increasing access to FBCs, not restricting it, and yet OHA cites Strong Start as justification for a set of proposed regulatory amendments that would do nothing other than restrict access to

Oregon FBCs. The Statement is therefore misleading in the implication that the proposed revisions will expand access to improve public health in Oregon in the ways that Strong Start shows that access to FBCs improve public health.

This is not the first time that OHA has revised regulations to restrict access to out-of-hospital birth, and issued a Statement of Need & Justification that inaccurately and misleadingly claims to be expanding access to those services. In April, 2020, OHA issued a "Temporary Administrative Order" to amend OAR 410-130-0240, the regulations that pertain to coverage of out-of-hospital maternal health services in Oregon. OHA used the mantle of the Covid emergency to forego a transparent rule-making process and amend the rules, later making the amendments permanent. The amendments to OAR 410-130-0240 dramatically decreased access to community birth by creating a long list of new medical risk factors that would cause OHP to deny coverage for community birth. The previous rules had stated that OHA would cover out-of-hospital births that were low-risk, and that the agency would look to the Tables for OAR 333-076-0650 to determine who is low risk. The Tables for OAR 333-076-0650 are the current Tables for scope of practice for licensed FBCs in Oregon. OHA's 2020 amendments to OAR 410-130-0240 created new Tables to guide coverage of FBC services, which listed many more clinical conditions that OHA would use to refuse coverage for FBC services. On their face, the 2020 Amendments to OAR 410-130-0240 dramatically reduced access to FBC services at a time when access to those services was critical to protecting public health.

And yet, as it does now, OHA issued a Statement of Need & Justification that falsely claimed that its proposed revisions would *expand* access in response to the Covid-19 pandemic and the Governor's order. It stated: "The Division needs to amend this rule to support appropriate response during an outbreak or epidemic of an infectious disease. This amended rule provides alternate criteria for coverage During the state of emergency under governor Kate Brown's executive order 20-03, to improve access to care, reduce exposure to Covid-19, and potentially reduce hospital utilization."

OHA's 2020 rule changes dramatically decreased access to FBC services at a time when the governor had ordered it to increase access. The Agency claimed that its rule changes expanded access to community birth, while its coverage administrators used the new rules to deny coverage for FBC services and direct OHP members to have their babies in the hospital. The Oregon Court of Appeals is currently hearing two consolidated appeals on behalf of six families who were denied coverage for FBC services at the height of the pandemic under OHA's amended rules, even though they were low risk and within scope for FBC services.[1] As the pleadings for that matter reflect, one Portland birth center provided care to 40 pregnant people

[1] *See Ely, Cox, Garcia and Pingel v. OHA*, Appellate Case No. A175618, and *Haugen and Norvell v. OHA*, Appellate Case No. A175820.

and babies who were within scope for FBC services, and OHP denied coverage, under its new rules, for all of them.

OABC is aware that different "departments" within OHA may be involved with amendments to OAR 410-130-0240 and amendments to OAR 333-076/077. Nevertheless, OHA is the administrative agency tasked with ensuring access to FBC services for pregnant patients under the ACA. OABC notes with concern the agency's pattern of restricting access to FBC services through regulatory amendments, while claiming to value those services and expand access to them in the Statements of Need & Justification accompanying those amendments.

OABC calls for any revisions to OAR Chapter 333 pertaining to licensure of FBCs that affect scope of care to reflect the medical evidence. Nothing about the Strong Start initiative justifies restricting access to FBC services; on the contrary, the evidence from that initiative demands improved access to FBC services in order to address the maternal health emergency that currently exists in the United States. Review of other studies pertaining to racial equity in maternal healthcare, and studies pertaining to FBC services, only strengthen and reinforce the need for expanded access.

b. Racial Equity Impact

The primary way that OHA claims to be protecting and advancing racial equity through the proposed rule changes is *by not taking away* vulnerable pregnant peoples' 1) right to receive prenatal care at FBCs, or their 2) right to give birth at FBCs after a previous cesarean section. OHA fails to mention that its proposed rule changes restrict access to FBC care in many other ways, and do not advance or improve access to FBCs in *any* way. Given the abundant evidence that access to midwifery care and community birth is essential to improving both physical and mental health outcomes for People of Color, OHA's proposed rule changes therefore undermine racial equity and will predictably exacerbate existing racial mortality disparities in Oregon.

OHA's "Statement Identifying How adoption of Rule(s) Will Affect Racial Equity In This State" cites statistics that suggest that Women of Color and people who depend on Medicaid are less likely to give birth at FBCs than white women and those who do not depend on Medicaid. OHA fails to mention that the agency itself has taken an active role in creating and enforcing this disparity in access to FBC services by those who depend on Medicaid, including People of Color, through its control over Medicaid coverage in the State of Oregon. Since at least 2016, OHA has failed and refused to follow the mandate of the Affordable Care Act to cover birth center services for OHP recipients to the extent that those services are within scope. Instead, it created and applied its own restrictive guidelines to decide who it would "allow" to give birth outside a hospital, broadly denying coverage to OHP members who were otherwise within scope and entitled to those services. *Id.* OHA's suggestion that FBC regulations are of minor concern for racial equity because People of Color do not give birth at FBCs is therefore disingenuous,

misleading, and dangerous in light of the realities that Families of Color are facing in hospital-based maternal healthcare in Oregon and the United States.

Incredibly, OHA's "Statement Identifying How adoption of Rule(s) Will Affect Racial Equity In This State" fails to mention that Women of Color are at an increased risk of death in pregnancy and childbirth in the United States and Oregon, with Black and Native American women facing significantly increased risks of maternal and perinatal death. Between 1999 and 2019, the maternal death rate among American Indians and Alaska Natives giving birth in Oregon rose 168% to 24.7 maternal deaths per 100,000 live births, while the maternal death rate for Black women rose 58% to 27.6 deaths per 100,000 live births. OHA's Statement cites the Strong Start Initiative for evidence that FBC care results in better outcomes for babies and their mothers, at lower costs to payers. And yet OHA concludes that its revisions to the rules will advance racial equity by "allowing [FBCs] to continue to provide prenatal care," and by requiring FBCs to consult with "perinatal providers" with regard to a long list of clinical factors. OHA does not mention that there is no evidence anywhere that making midwives consult regarding their clients' care will improve outcomes or racial equity, or demonstrate any concern that the increased costs of the many administrative burdens imposed under the proposed revised rules will undermine access to care.

The leading causes of maternal death in Oregon, as elsewhere in the United States, are 1) mental health and suicide, 2) amniotic fluid embolism (AFE), and 3) hemorrhage.[2] The risk of AFE is almost doubled following a surgical delivery as compared to a vaginal delivery; like hemorrhage, it is also associated with the risks that surgical deliveries create for subsequent pregnancies such as placenta accreta. The rate of maternal death causally related to mode of delivery is 1200% higher with cesarean surgery than vaginal birth.[3] Oregon's Maternal Mortality and Morbidity Review Committee Biennial Report from January 2023 admits that cesarean deliveries are causally associated with maternal mortality and morbidity. *Id.* at p.28. The overuse of cesarean surgery is widely acknowledged to contribute to America's maternal mortality crisis.[4]

OHA acknowledges that women who give birth at an FBC have a much lower risk, "by far," of giving birth by cesarean surgery as compared to low-risk women giving birth in the hospital setting. Protecting and increasing access to FBC care and midwifery care—not just for pregnancy, but for childbirth— is essential for minimizing the risks that cause racial mortality disparities in U.S. maternity care.[5] Black women experience a higher rate of primary cesarean deliveries compared to white women, even after accounting for clinical risk and

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[2] https://www.oregon.gov/oha/PH/HEALTHYPEOPLEFAMILIES/DATAREPORTS/MCHTITLEV/Documents/January2023BiennielReportMMRCFinal.pdf

[3] https://pubmed.ncbi.nlm.nih.gov/18455140/

[4] https://digitalcommons.du.edu/cgi/viewcontent.cgi?article=1014&context=undergraduate_theses

[5] https://commonsensechildbirth.org/wp-content/uploads/2022/03/Groundswell_Report_final_online.pdf

sociodemographic factors; protecting their access to FBC services reduces the risk of cesarean and therefore, the risk of preventable mortality.

People of color are at increased risks of mental health disorders due, in part, to the stressors of racism.[6] With regard to reducing risks to maternal mental health, OHA cites no evidence for its claim that requiring FBCs to consult with outside providers for clients with mental health histories will "ensure the connection of physical, mental and social well-being." OHA fails to recognize that protecting access to FBCs and culturally safe midwifery care is the proven way to "ensure the connection of physical, mental, and social well-being," because the midwifery model of care is founded on that connection. Midwives do not need to consult with other provider types in order to provide holistic care that looks after the physical, mental, and social well-being of their clients. By forcing FBCs to do so, OHA would do nothing more than increase healthcare costs and barriers to access for the women who want, and need, FBC services, predictably driving them into care that is proven to be deleterious to their mental health. Better solutions to addressing mental health concerns in pregnancy would be to reimburse a counseling code for additional one-on-one time with their midwife or FBC provider, and to guarantee comprehensive doula/ THW care that enables the doula to make a long-term support plan for the patient's mental health needs after postpartum care ends.

In short, OHA's Statement regarding the impact of the proposed rules on Racial Equity is misleading. It fails to cite the abundant evidence that increasing and protecting access to midwifery care, especially culturally safe midwifery care, is the key to reducing racial mortality disparities in maternal healthcare. OHA cites one piece of evidence, the Strong Start Initiative, which proves better outcomes at lower costs for FBC patients, but OHA then misleadingly suggests that the new rules implement that evidence by protecting access to FBC services for communities of color in Oregon. The truth is that the proposed rules will predictably restrict access and increase the costs of FBC services.

Because the proposed rules restrict access and increase the costs of FBC services, they will have a negative effect on racial equity in the State of Oregon. If OHA is interested in advancing racial equity in reproductive healthcare, it will withdraw the amendments that take informed choice away from patients by requiring FBCs to turn them away, and withdraw the rules that micromanage FBC providers' shared decision-making with their clients. OHA's regulation of FBCs is openly discriminatory because it does not regulate hospital-based providers clinical decision-making, or second-guess their ability to assess their clients' needs. The discrimination against FBC providers that is apparent in the draft regulations' consultation requirements will predictably serve to reinforce the structural discrimination that causes

[6] Williams DR. Stress and the Mental Health of Populations of Color: Advancing Our Understanding of Race-related Stressors. J Health Soc Behav. 2018 Dec;59(4):466-485. doi: 10.1177/0022146518814251; https://mhanational.org/resources/racism-and-mental-health/

preventable death for women and babies in this state, especially for women and babies from historically marginalized communities.

Fiscal Impact

OHA's Statement acknowledges that the proposed revisions to the FBC rules create many new administrative burdens that will impose new costs on birth centers. In addition to the costs created by new consultation requirements—requirements that OHA does not impose on midwives and other providers of the same maternal health services in the hospital setting—the proposed revisions impose facility requirements that OHA does not demand of hospitals or obstetric clinics, like the creation of a children's play area in the waiting room. The irony is that midwives and FBCs are the most likely of provider types to maintain a children's play area for their clients, because of midwives' focus on the whole health of the family. However, for OHA to *require* FBCs to create one, when it does not require this of hospitals or obstetric clinics, is openly discriminatory toward FBCs.

Maintaining coverage discrimination while revising Oregon regulations to increase costs to FBCs will predictably lead to the closure of some Oregon FBCs, further decreasing access to these critical services. OHA is well aware that Oregon FBCs operate on a very slim financial margin, as a result of OHA's own broad refusal to cover FBC services in violation of Section 2301 of the ACA, and as a result of ongoing discrimination by private payers in violation of Section 2706 of the ACA. If OHA were concerned with improving maternal and perinatal health outcomes in Oregon, it would eliminate coverage discrimination within its own agency, and work with Oregon's Insurance Commissioner to require private payers and group health plans to follow the Harkin Amendment in this State.

OHA's Fiscal Impact statement is disingenuous in the suggestion that it is uncertain whether the proposed revisions would impact the public. The Statement's claim that "it is possible that clients of [FBCs] may see an increase in cost if licensed [FBCs] choose to pass down any costs associated with increased licensing standards" feigns ignorance of how FBCs, hospitals, medical clinics, and all healthcare facilities price their services, and the fact that the cost of services to the consumer is a function of the cost of providing those services. The only way that increasing the costs of FBC operations would not increase the cost of FBC services would be if FBCs ate those costs in a way that hospitals would never do. OHA's suggestion that FBCs should themselves carry the costs of regulatory compliance, and further reduce their very slim operating margins, reflects OHA's lack of concern with the continued operation of FBCs in Oregon. Driving FBCs out of business through administrative costs will not advance public health or racial equity in Oregon. Nor will increasing the costs of FBC services in Oregon, unless those services are reliably covered by OHP and the other payers on whom FBC clients rely.

III. Comments on Proposed Amendments to Tables I – III on FBC Scope of Services

A primary purpose of the RAC for these proposed rules was to ensure that decisions about FBCs scope of practice were informed by the providers with knowledge and experience with providing care in the community setting, and informed by evidence that justified any restriction on access to FBC services. Review of the current drafts of the OAR 333-077-0125 Tables that would require transfer or consultation for a long list of medical conditions indicates that OHA simply ignored the feedback of the RAC on many of the medical issues that are included in the current draft Tables. At no time has OHA or anybody on the RAC presented any medical evidence that these restrictions are necessary to protect public health. At no time has OHA indicated that there were any negative outcomes under the current regulations and tables that determine FBC scope in Oregon, that would justify restricting that scope in the new rules. New rules that require FBCs to turn pregnant people away, rather than support pregnant people in informed decision-making about the risks of their options for care, decreases rather than improves safety. RAC members with familiarity with community birth reported over the years of the RAC meetings that more and more families are choosing to give birth unassisted rather than be forced into hospital care and its associated risks. The proposed regulations would predictably increase these numbers, and thereby cause the preventable deaths that will occur in unassisted home birth.

Specifically, OABC objects to the following provisions of the proposed Tables under OAR 333-077-0125:

Table I: Medical History or Obstetric History:

1. Delivery History:
    a. OABC objects that "history of cesarean section and complications *including* [a limited list]" should be moved out of transfer and into a consultation. There are a wide range of "complications" that can occur with a prior cesarean, including e.g. an anesthesia failure, that should not require hospital birth in a subsequent pregnancy. Consultation allows for an individualized risk analysis and client-centered decision-making.
    b. "Hysterotomy, other than cesarean": On January 24, 2020, the RAC voted to move "other hysterotomy" to a consultation. For reasons similar to those stated above, the risks created by prior hysterotomy can be widely variable, and OHA has not produced any evidence that would justify denying the patient the right to make an informed decision.
2. Diabetes, Type 2. On March 2, 2020, the RAC voted that Type II diabetes should be a consultation if it is uncontrolled or controlled with other than oral medication. OABC objects to including Type 2 diabetes currently requiring oral medication as a requirement for transfer. At no time has OHA presented evidence or argument that would warrant

doing otherwise. OABC stands by the decision of the RAC, and requests amendment to this language to accord with the committee's vote.

3. Neurological disorders: The draft regulations that were reviewed for *five years* in the RAC process did not contain any provision to consult or transfer clients with "neurologic disorders." OHA added this to its final draft rules without any proposal or discussion with the RAC. OABC objects to the inclusion of any neurologic disorders as requiring transfer, but would accept their inclusion as a consultation. As with most conditions of pregnancy, there are risks and benefits of hospital and out-of-hospital birth for patients with, e.g. myasthenia gravis, because while there is an unquantified increase in the risk of maternal exhaustion in the second stage and neonatal respiratory distress, patients with myasthenia gravis have a strong interest in minimizing their risk of surgical delivery—which is best accomplished through community birth—because surgical delivery can worsen the condition or cause a myasthenic crisis in the birthing patient. OHA has never presented any evidence that would justify suddenly forbidding FBCs to care for patients with any history of neurological conditions, or in taking away the patient's right to informed decision-making. OABC therefore recommends including neurologic conditions as a consultation, if they are added to the proposed rules at all.
4. Prior stillbirth/ neonatal death: On March 2, 2020, the RAC voted that the language "prior stillbirth/ neonatal death" was inappropriate as a grounds to require either transfer or consultation. The RAC voted that consultation would be reasonable for "stillbirth or neonatal death (unexplained) or previous death related to intrapartum difficulty." OABC stands by the decision of the RAC, and requests amendment to this language.

Table II: Conditions of Current Pregnancy:

1. Abnormal bleeding in pregnancy: On November 29, 2021, 100% of the RAC voted to move "antepartum hemorrhage, recurrent" to a consultation. At no time has OHA presented evidence or argument that would warrant doing otherwise. OABC stands by the decision of the RAC, and requests amendment to this language to accord with the committee's vote.
2. Amniotic Fluid Rupture – Pre-labor rupture >24 hours: On November 29, 2021, 100% of the RAC voted against including this as a requirement for transfer, and 75% of the RAC voted against making it a requirement for consultation. The feedback of the RAC was that the evidence supported consultation after 72 hours, or earlier in the presence of signs or symptoms of infection. OABC suggests editing this to "Pre-labor rupture > 48 hours" to better accord with the recommendations of the RAC.
3. Hematologic conditions – Thrombocytopenia (platelets < 100,000): On March 2, 2020, 91% of the RAC voted against including "Thrombocytopenia (platelets < 100,000)" as a requirement for transfer of care. 91% of the RAC voted for including "Thrombocytopenia (platelets < 75,000)" as an indication for transfer. At no time has OHA presented evidence

or argument that would warrant doing otherwise. OABC stands by the decision of the RAC, and requests amendment to this language to accord with the committee's vote.

4. Fetal Growth – IUGR – fetal weight less than 5th percentile using ethnically-appropriate growth table, or concerning reduced growth velocity on ultrasound:" On August 3, 2020, 100% of the RAC voted to put this indication as a requirement for a consultation, rather than a requirement for transfer of care. At no time has OHA presented evidence or argument that would warrant doing otherwise. OABC stands by the decision of the RAC, and requests amendment to this language to accord with the committee's vote.
5. Fetal Presentation/ Multiple Gestations: The RAC first discussed the proposal for including mandatory transfer for breech or multiples on August 3, 2020. After extensive discussion about the fact that many Oregon hospitals force women into cesareans if they are carrying multiples or breech babies, and pregnant patients' strong desire for options and informed choice with breech or multiples pregnancies, a vote on the inclusion of these risk factors was deferred at that time. Although not all Oregon FBCs will offer breech and twin deliveries, some RAC members expressed that, in their part of the state, community birth is the only option for vaginal birth. Because FBCs are often closer to hospitals and more highly resourced than home births, allowing FBCs the discretion to offer this service protects public health.

   The issue was revisited on October 4, 2022. At no time did OHA present evidence or argument that safety or public health are protected by requiring women with breech or multiples to give birth in the hospital setting. On October 4, 2022, 84% of the RAC voted against including "multiples" as a requirement for transfer, and 73% of the RAC voted against including "non-cephalic presentation" as a requirement for transfer. At no time has OHA presented evidence or argument that would warrant doing otherwise. OABC stands by the decision of the RAC, and requests amendment to this language to accord with the committee's vote, by moving Fetal Presentation and Multiples into indications for consultation, rather than requirements for transfer.

   OABC notes that the proposed rules create confusion, medical risk for birthing people and their babies, and legal risk for birth centers, by removing the following notation from the draft that was discussed during the RAC meetings: "Imminent fetal delivery may delay or preclude actual transfer prior to birth." The new FBC regulations *must* include a notation that this principle applies to all decisions about intrapartum transfer of care. When this point was raised during the August 3, 2020 RAC, the minutes for that meeting reflect that "staff noted that for any of the risk factors, if birth is imminent and risk for transferring is higher, then the birth center should follow through with the birth." OABC strongly requests the inclusion of this language in the new rules, in order to protect FBC providers' ability to make decisions about transfer that protect the safety of their clients and their babies.

6. Gestational Age: On August 3, 2020, the RAC expressed strong concerns about the proposed revision of the current rule, which allows FBCs to care for patients after 42 weeks gestation if a non-stress test indicates the pregnancy remains normal, to require FBCs to transfer clients out of care if their pregnancy goes past 42 weeks. A vote on the issue was deferred. When the question was revisited, on October 4, 2022, the RAC voted against amending the rule to require transfer after 42 weeks. At no time has OHA presented evidence or argument that would warrant doing otherwise.

   As with breech and twin pregnancies, this issue is critical to reproductive justice because of the informed consent violations and "required" interventions that pregnant patients face in the hospital setting. Like cesarean section, induction of labor is overused in American obstetric care for reasons of provider convenience, creating unnecessary risks for pregnant people and their babies.[7] A 2023 study showed that the overuse of induction in the United States reduced the average age of gestation by one full week between 1990 and 2020, without improving outcomes relative to the United Kingdom and the Netherlands, which maternal health systems that "allow" women to carry their pregnancies to term.[8] Strikingly, the study showed that only 5% of pregnant women who give birth today in U.S. hospitals manage to carry pregnancies to 41 weeks, and *0% of women who give birth in U.S. hospitals manage to carry their pregnancies to 42 weeks and beyond*. In the community setting, the study showed that 17% of women will carry their pregnancies to 41 weeks, and 3% will remain pregnant to 42 weeks or beyond. *Id.*

   Community birth is therefore the only setting where many women will find support for making an informed decision to go into labor naturally rather than induce, when the pregnancy otherwise remains healthy but goes past 42 weeks. Requiring FBCs to deny care to women whose pregnancies go beyond 42 weeks will force those patients to choose between unwanted induction of labor or unwanted home or unassisted birth. OABC stands by the decision of the RAC to put pregnancy beyond 42 weeks gestation as a consultation, and requests amendment to this language to accord with the committee's vote.

7. Hypertension: At the RAC meeting on September 13, 2021, 0% of the Committee found it acceptable to include, as a risk factor requiring transfer, "pregnancy induced hypertension with diastolic blood pressure at or above 90mmHg or systolic blood pressure at or above 140mmHg on two consecutive readings taken at least 30 minutes apart." OHA was reminded that mild hypertension is not pre-eclampsia or eclampsia, and that midwives and other FBC providers have the ability to test or monitor for eclampsia,

[7] See, e.g., https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2015/01/23/09/03/reducing-non-medically-indicated-elective-inductions-of-labor#:~:text=Rates%20of%20induced%20labor%20have,of%20non%2Dmedically%20indicated%20inductions.
[8] See Declerq, E., Shah, N. et al., "The Natural Pattern of birth timing and gestational age in the U.S. compared to England and the Netherlands," PLoS One 2023 Jan 18;18(1):e0278856. https://pubmed.ncbi.nlm.nih.gov/36652413/

and to inform their clients of their options for induction or expectant management. The recommendation of the RAC was to put hypertension with diastolic blood pressure at or above 90mmHg or systolic blood pressure at or above 140mmHg on two consecutive readings taken at least four hours apart as a consultation requirement. At no time has OHA presented evidence or argument that would warrant doing otherwise. OABC stands by the decision of the RAC, and requests amendment to this language to accord with the committee's vote.

8. Infectious Conditions:
    a. Hepatitis B: At the September 13, 2021 RAC meeting, 90% of the RAC voted against including unknown Hepatitis B status as a requirement for transfer, and 70% of the RAC voted against including positive status for Hepatitis B as a requirement for transfer in all cases. At no time has OHA presented evidence or argument that would warrant doing otherwise. OABC stands by the decision of the RAC, and requests amendment to this language to accord with the committee's vote.
    b. Syphilis: On October 18, 2021, the RAC voted to put this condition in the category for consultation, and/or to only have "untreated Syphilis" included as a risk factor requiring transfer. At no time has OHA presented evidence or argument that would warrant doing otherwise. OABC stands by the decision of the RAC, and requests amendment to this language to accord with the committee's vote.
    c. Shingles: Shingles was not included as a proposed indication for transfer in the draft rules circulated over the five years of the RAC meetings. On October 18, 2021, OHA proposed including the condition as a requirement for consultation, and the RAC voted that that would be acceptable. At no time was the idea of putting it as a risk factor requiring transfer discussed, and yet OHA injected it into the current draft tables. At no time has OHA presented evidence or argument that would warrant denying care to all patients with shingles. OABC stands by the decision of the RAC, and requests amendment to this language to accord with the committee's vote.
9. Placental Conditions:
    a. On November 29, 2021, the RAC voted to remove requirements relating to the location of the placenta "at term" with the location of the placenta "at the last ultrasound prior to the start of labor." This principle applies to placenta previa and vasa previa as well. Placentas that are identified to be located near the cervical os at a 20-week ultrasound usually move before 34 weeks of gestation. If they do not move, transfer of care is necessary at that time. There is no evidence basis for requiring FBCs to deny care to patients with placenta previa or low-lying placentas if those placentas subsequently move into a normal location. OABC therefore asks this provision to align with medical evidence and midwifery

standards of care by adding "at the last ultrasound prior to the start of labor" to qualify the requirement to transfer low-lying placentas and previas.

10. Labor Management – Lack of adequate progress in 2nd stage with cephalic presentation.
    a. On February 15, 2022, 100% of the RAC rejected a requirement to transfer patients for "failure to progress." The RAC made clear that "lack of adequate progress in 2nd stage" could only be acceptable if "lack of adequate progress" is defined, as it is in the DEM rules: "which means no descent after a maximum of three hours of active pushing in cases with complete dilation and ruptured membranes." This definition is essential to protecting midwives' clinical judgment, as midwives assess timeframes for progress differently than obstetricians and hospitals do, and pregnant patients seek midwifery care for this reason. OABC therefore requests that this indication be amended to mirror the DEM rule: "lack of adequate progress in 2nd stage, which means no descent after a maximum of three hours of active pushing in cases with complete dilation and ruptured membranes."
11. Perineal laceration – Enlarging Hematoma: On January 20, 2022, 91% of the RAC voted against including "enlarging hematoma" as a risk factor requiring transfer of care. At no time has OHA presented evidence or argument that would warrant doing otherwise. OABC stands by the decision of the RAC, and requests amendment to this language to accord with the committee's vote by either removing it altogether or placing it as a consultation.

We have additional concerns on the following changes to facility regulations:

Section OAR 333-077-0160 Dietary ServicesSection 3 B an and d require only prepackaged meals be served and only single use utensils used. It is not culturally appropriate for all birth center clients to be served this type of food as many birthing people follow a specialized meal plan the first 4-6 weeks after giving the birth that excludes foods in direct contact with plastic. We believe that single-use service-ware and prepackaged meals will create a financial burden, particularly for startup birth centers, and detract from the efficacy, nutritional quality, and customization of each meal that we serve. We propose as an alternative that birth centers continue to be able to prepare and serve food and that all staff be required to obtain and maintain a food-handler's card.

0025 4 (b), it would appear that OHA wishes to assert that we may not provide any services not already regulated by OHA through the clinics in our facilities. We would like to have this removed or to have clear wording that we are allowed to provide any services within our scope of practice whether or not OHA directly or indirectly regulates them. For clarity, we wish to know if OHA is viewing the facility as the same as the clinic. We are concerned that OHA may be over-asserting control over what we can and can't do. While we all agree that we

will not provide services outside of our scope of practice or the absolute risk tables, there are services which OHA does not regulate, which may be beneficial, which we would like to continue to offer as long as they are otherwise legal.

5035 5 (a), indicated that a birth center would have to start from scratch if they don't resubmit licensure by the annual deadline. We wish to include a 90-day relicensure grace period in the event of an extenuating circumstance arises that would allow a renewal rather than having to submit a new license applications; and that OHA would inform us via mail, email and phone if renewal is not received by November 15th.

333-077-022Physical Environment:

Section B: Requires a children's play area. It is unreasonable to include this in rule. Birth centers should simply be required to have an adequate waiting area.

Section 2 b + c from the statement of need: This needs to include wording to indicate OHA will work with OHP and all private Medicaid plans to ensure facility reimbursement increases to cover the increased costs associated with running a birth center. This is especially important as a black owned birth center is in the early stage of planning and opening and it is not equitable for them to be the first facility to have to adhere to all the new rules but to be paid at the level that was determined before these changes.

OABC appreciates the opportunity to participate in the Rulemaking Advisory Committee that has helped OHA shape the proposed amendments to Oregon's freestanding birth center rules from May 2019 to the present. We continue to be available to the agency and the committee involved with the proposed rules to discuss the finalization of the rules. As discussed throughout this memorandum, we hope that the final version of the rules will reflect the input of the RAC, protect the rights and health of women and birthing people in Oregon, and advance reproductive justice and racial equity by ensuring access to FBC services for as many families as possible.

Sincerely,

/s/ Hermine Hayes-Klein

Hermine Hayes-Klein

/s/ Karen DeWitt

Karen DeWitt
Oregon Association of Birth Centers
[redacted]

/s/ Desiree Lefave

Desiree Lefave, RAC Member

/s/ Tierra Salmón

Tierra Salmon, RAC member

March 15, 2025

OHA – Public Health Division
Attn: Mellony Bernal
800 NE Oregon Street, Suite 930
Portland, OR 97232
publichealth.rules@odhsoha.oregon.gov

Re: Proposed Permanent Rulemaking – OAR chapter 333, divisions 76 and 77, "Freestanding Birthing Center Licensure Requirements"

Dear Mellony Bernal,

Thank you for the opportunity to comment on these proposed regulations for freestanding birth centers in Oregon. The American Association of Birth Centers (AABC) has national expertise and decades of experience in the safe operation of birth centers. We appreciate the work of all the stakeholders involved in the revision process.

AABC is committed to ensuring safe, high-quality, family-centered options for birth center care through regulations aligned with the nationally recognized AABC Standards. Access to the birth center option for pregnant people depends on public trust and viable birth center models, along with regulation and licensure that ensure quality and safety but do not create barriers to access to care. We support the detailed work of the Oregon Birth Center Association and their comments on these proposed regulations.

In addition, we provide the following comments:

- 333-077-0125 – Table II
    - Consultation for patients on psychotropic medications - The prevalence of behavioral health conditions is widespread among patients who are lower risk and who qualify for birth center care by risk factors. Studies have estimated that 10% of all pregnant patients take some type of psychotropic medication. Birth center midwives are educated and trained to consult appropriately when a patient has any co-existing health condition that may impact pregnancy, labor and birth. The requirement to consult with a perinatal healthcare provider for a patient taking a psychotropic medication seems overly broad. It should be determined by considering the individual clinical situation, clinical practice guidelines, and co-management with the patient's mental health provider. Certified Nurse-Midwives, Certified Professional Midwives, and Naturopathic Physicians all have the knowledge and skills within their scope of practice to assess, consult, and transfer when necessary. The proposed regulation does not align with AABC Standards.

- 33-077-0160: Dietary Services
    - The AABC Birth Center Standards support that birth centers be a homelike setting, which is covered in Standard 4. Equipment and Furnishings. It states that in addition to the necessary equipment for safe care of the mother and newborn, "The birth center has properly maintained accessory equipment which includes but is not limited to: a) Conveniently placed telecommunication device b) Portable lighting including an emergency light source c) Kitchen equipment usually found in home for light refreshment. This Standard does not require that a kitchen in a birth center be certified by the state as meeting the requirements of a certified restaurant or other institutional kitchen. For birth centers located in rural communities, the requirement that food be prepared in a certified restaurant kitchen is not feasible. This requirement is overly strict and does not align with AABC Standards.
    - The requirement for only single service utensils to be used is not environmentally friendly. Patients seek birth center care because they want individualized and personalized care. The use of single service utensils or food packaging may not meet the needs of all patients or situations and stainless steel silverware should be acceptable. The birth center is a home-like setting that is not a hospital. This proposed regulation does not align with AABC Standards and will not improve the health of birth center patients.

AABC has developed resources for states developing or revising birth center regulations. We recommend the Department of Health review the AABC Toolkit: Best Practices in Birth Center Regulations. It provides materials that define key terms, review common regulatory barriers and introduce model regulatory language to align birth center licensing with best practices and national standards. Access the toolkit at https://www.birthcenters.org/products/toolkit-regs.

Thank you for the opportunity to comment on the proposed revisions to the regulations for licensing birth centers. We are available to answer any questions you may have about these or other changes in the future. Our hope is that these new regulations preserve high-quality, evidence-based care that promotes increased access and decreased disparities.

Respectfully,

Kate Bauer
Executive Director, AABC

Jill Alliman, DNP, CNM, FACNM
Government Affairs Committee Chair, AABC

From: HALL Brittany A
To: Public Health Rules
Subject: FW: Proposed Rulemaking regarding Birth Centers
Date: Tuesday, March 11, 2025 3:40:03 PM

From: OSBN PracticeQuestion * OSBN <osbn.practicequestion@osbn.oregon.gov>
Sent: Tuesday, March 11, 2025 8:48 AM
To: [redacted]
Cc: Mellony Bernal <MELLONY.C.BERNAL@oha.oregon.gov>
Subject: RE: Proposed Rulemaking regarding Birth Centers

> You don't often get email from osbn.practicequestion@osbn.oregon.gov. Learn why this is important

Thank you for your patience Mary Kay as I have been out on medical leave.

The proposed rule changes specify **newborn follow-up visits at two weeks and between 6-8 weeks**. However, Oregon's **Direct Entry Midwifery (DEM) Rules (OAR 332-010-040)** and **ACNM standards** define a **newborn as a child less than 28 days old**. If the rule is enacted, birth centers may need to **clarify scope alignment** with these established definitions.
Reference: OAR 332-010-040, ACNM Scope of Practice

The written comment period to receive comments on the Notice of Proposed Permanent Rulemaking – OAR chapter 333, divisions 76 and 77, "Freestanding Birthing Center Licensure Requirements" has been **extended to 5:00 P.M. Pacific Time on March 17, 2025**.

If you would like to let them know of your concerns on this issue:
Details on how to submit written comments are provided in the attached "333-076 077_Notice to IPs extension of comment period FINAL" document and can also be found on OHA's rulemaking activity page at http://www.healthoregon.org/hcrqirules, under Proposed Rules Out for Public Comment.

Additionally, I have cc'd your comment and my response to my colleague on OHA's staff.

Sincerely,
Sarah Wickenhagen, DNP, APRN, FNP-C

Advanced Practice Policy Analyst

Helpful OSBN links:
OSBN Website
File a Complaint
Oregon Nurse Practice Act : State of Oregon
Mental Health Resources for Nurses

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Vision: A safe and healthy Oregon promoted through a healthy and diverse nursing workforce.

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From: MaryKay CMO <[redacted]>
Sent: Sunday, January 5, 2025 8:28 AM
To: OSBN Oregon BN Info * OSBN <oregon.bn.info@osbn.oregon.gov>
Subject: Proposed Rulemaking regarding Birth Centers

> You don't often get email from [redacted] Learn why this is important

Greetings,
I received an email notifying me of proposed changes to birth center rules. I have a question

about follow-up newborn care. The Statement of Need and Fiscal Impact notes the following:

“Specifies newborn follow-up visits at two weeks and between 6-8 weeks.”

Will this require a birth center to provide newborn care up to 6-8 weeks? It is my understanding that this would not be in keeping with current Oregon DEM Rules and ACNM Standards.

1- The Oregon Board of Direct Entry Midwifery Rules (unofficial, user-friendly copy) - OAR Chapter 332, Divisions 010-040, page 3, defines a "Newborn" as a child less than one month of age. The Administrative Rules go on to mention how newborns are cared for under the General Practice Standards, Risk Assessment Practice Standards, Care Practice Standards, and Records of Care Practice Standards.

2- The American College of Nurse-Midwives “The Definition of Midwifery and Scope of Practice of Certified Nurse-Midwives and Certified Midwives,” document includes in the scope of practice, “care for the healthy newborn during the first 28 days of life.”

These documents are consistent with the definition of newborn as the first 28 days of life, by the World Health Organization and other professional organizations.

Here is a link to the DEM Rules and ACNM Core Competencies documents.
https://drive.google.com/drive/folders/10SLiFHlfY6myYM6QlLibU9KTzJFbMPNu?usp=drive_link

Thank you for your response,

MaryKay Ayers

-

MaryKay Ayers, CNM, DNP

Chief Midwifery Officer
[redacted] // birthpartners.com

Birth Partners, INC
[redacted]
Westchester, IL 60154
[redacted]

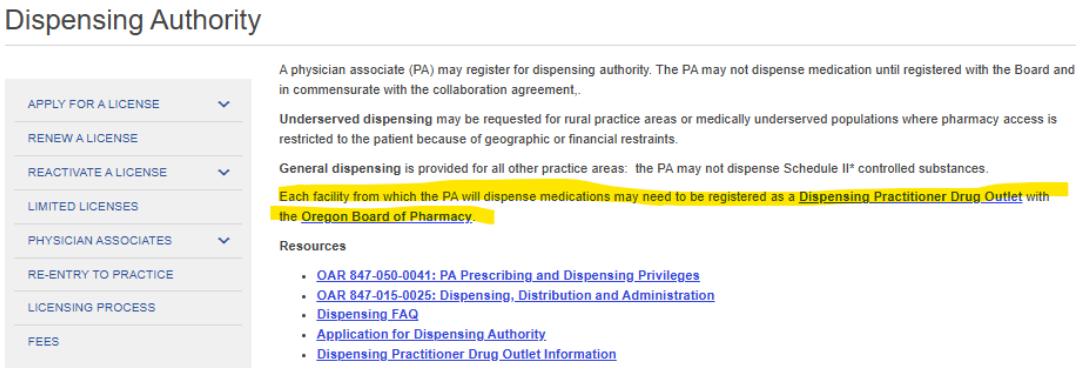
From: HALL Brittany A
To: Public Health Rules
Subject: FW: 333-077-0150 > RE: Notice of Proposed Rulemaking - Freestanding Birthing Centers
Date: Monday, February 3, 2025 9:27:54 AM
Attachments: image001.png
image003.png
Importance: High

From: RUNYON Gary * BOP <Gary.RUNYON@bop.oregon.gov>
Sent: Monday, February 3, 2025 8:11 AM
To: Mellony Bernal <MELLONY.C.BERNAL@oha.oregon.gov>
Subject: RE: 333-077-0150 > RE: Notice of Proposed Rulemaking - Freestanding Birthing Centers
Importance: High

Mellony,

After internal review and discussion of the proposed rule amendments for OAR 333-077-0150, I think there are several additional considerations that might be beneficial to entertain as a final iteration of these rules is constructed. Of note, there were a few points in particular that might need additional scrutiny:

- **Clear division of accountability between practitioner and outlet (i.e., birthing center):** In many instances, it is unclear who might be responsible for certain elements within the continuum of care, or whether certain duties should be a responsibility of the licensee or would be more appropriately covered in the policies and procedures for the outlet. For example, the rules for many prescribing and dispensing practitioners might mention parameters for the judicious use of controlled substances, however these rules might not address specific requirements for the prevention of diversion, such as conducting a routine inventory and reconciliation, much less what interval for such is acceptable, and what should be done with that information. Due to limited resources, I'm unable to help determine exactly where these disparities might lie, but I think it might be beneficial to further consider.
- **Scope of licensure versus registration:** In some instances, a practitioner might be providing a service that is within their scope of primary licensure but may also require registration with another health professional licensing board, or other entity. It might be beneficial to highlight this in the rules, even with a general statement such as the one in the previous sentence. Since there will be multiple types of providers working at these centers, in determining how you might want to approach that, you might first want to consider whether that responsibility should lie on the birthing center or would be more appropriate to place on the licensee practicing within the facility. (see screenshot below from the OMB website, referring PAs to the Oregon Board of Pharmacy Website for registration as a Dispensing Practitioner Drug Outlet, or DPDO; though this might be required of other licensees if certain criteria are met, I am unsure as to whether it is mentioned in the rules for each type.
- **Drug Procurement:** it is unclear who is responsible for ensuring procurement standards for medications used in the center, or what those standards might be. After a quick scan of the rules related to various prescribing and dispensing practitioners, drug procurement is not consistently addressed. In many instances, in our Board of Pharmacy Rules, this lies on the outlet and might be addressed in their policies and procedures. See our DPDO Rules in OAR 855-043-0530, for example, where it states: "The registered DPDO may only receive drugs from an Oregon Registered Drug Outlet (e.g. Wholesaler, Manufacturer or Pharmacy)."
- **Clarity on prescription labeling:** there are some inconsistencies in the labeling requirements. In one instance, the rules require an expiration date be assigned only when applicable, while in another, they seem to require it for all medications. Additionally, there seems to be an exception to requiring the "quantity per unit" for compounded medications, and I'm unsure as to what the intent was there. For more information, ORS 677.089, **855-041-1105(2)(a)-(g) and OAR 855-043-0540.**
- **Compounded medications:** Generally speaking, the licensing boards for many prescribing and dispensing practitioners do not directly address compounding practices or require that their licensees adhere to a particular standard like USP. For example, I do not believe that the OMB rules in OAR Chapter 847 address compounding at all. If compounding is permitted in these centers, it might be worth further considering some sort of standard.



I hope this is helpful. Please reach out if you have any additional questions. Take care.

Thank you,

Gary Runyon, Pharm.D., R.Ph.
Pharmacist Consultant
Oregon Board of Pharmacy
Gary.Runyon@bop.oregon.gov

(971) 673-0001
Oregon.Gov/Pharmacy

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From: Public Health Rules
To: Public Health Rules
Subject: RE: Is out of hospital VBAC considered a low risk delivery type according to the HERC?
Date: Friday, January 31, 2025 8:31:48 AM
Attachments: image001.png

From: Sharron Fuchs <[redacted]>
Sent: Thursday, January 30, 2025 10:58 AM
To: Selover Dana S <DANA.S.SELOVER@oha.oregon.gov>; Mellony Bernal <MELLONY.C.BERNAL@oha.oregon.gov>; Jason Gingerich <JASON.D.GINGERICH@oha.oregon.gov>; Mautner Dawn <Dawn.Mautner@oha.oregon.gov>
Subject: Fwd: Is out of hospital VBAC considered a low risk delivery type according to the HERC?

Dear Dr. Selover,

Please see my email to Jason Gingerich of the Oregon Health Evidence Review Commission and his response below.

The **Oregon Health Evidence Review Commission** (HERC) in 2014 was assigned the task by several members of the Oregon Legislature to conduct a thorough review of all available information and develop the criteria for the definition of low risk out of hospital birth (see link below for history). This task was requested after the **Licensed Direct Entry Midwifery Staff Advisory Group** issued their final report (see link and highlighted screenshot below for history and report). In 2015 HERC completed its first review and issued a list of criteria needed to be met in order to define an out of hospital birth low risk . The HERC low risk criteria applied to all payers (see screenshot below with highlights). In 2017 I was a member of the **Out of Hospital Births Workgroup** which based its work on the low risk criteria developed by the two groups named above (see link below for report).

That said, according to the multi year medical review (2015) and multi year medical re-review (2020) , the **Oregon Health Evidence Review Commission (HERC) affirmed and reaffirmed that any type of vaginal birth after c-section was high risk.**

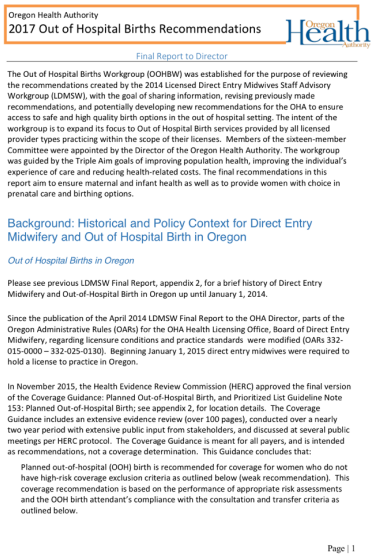
The state of Oregon through the Oregon Health Evidence Review Commission was the first in the nation to formally list and adopt the criteria for the definition of low risk out of hospital births. All births in birth centers by law are to be low risk , regardless of payer.

I respectfully request that the draft Birth Center Administrative Rules be revised and

remove the high risk Vaginal Birth after C-section in compliance with Oregon law.

Very truly yours,

Sharron Fuchs
Public Citizen



Oregon Health Authority
2017 Out of Hospital Births Recommendations

Final Report to Director

The Out of Hospital Births Workgroup (OOHBW) was established for the purpose of reviewing the recommendations created by the 2014 Licensed Direct Entry Midwives Staff Advisory Workgroup (LDMSW), with the goal of sharing information, revising previously made recommendations, and potentially developing new recommendations for the OHA to ensure access to safe and high quality birth options in the out of hospital setting. The intent of the workgroup is to expand its focus to Out of Hospital Birth services provided by all licensed provider types practicing within the scope of their licenses. Members of the sixteen-member Committee were appointed by the Director of the Oregon Health Authority. The workgroup was guided by the Triple Aim goals of improving population health, improving the individual's experience of care and reducing health-related costs. The final recommendations in this report aim to ensure maternal and infant health as well as to provide women with choice in prenatal care and birthing options.

Background: Historical and Policy Context for Direct Entry Midwifery and Out of Hospital Birth in Oregon

Out of Hospital Births in Oregon

Please see previous LDMSW Final Report, appendix 2, for a brief history of Direct Entry Midwifery and Out-of-Hospital Birth in Oregon up until January 1, 2014.

Since the publication of the April 2014 LDMSW Final Report to the OHA Director, parts of the Oregon Administrative Rules (OARs) for the OHA Health Licensing Office, Board of Direct Entry Midwifery, regarding licensure conditions and practice standards were modified (OARs 332-015-0000 – 332-025-0130). Beginning January 1, 2015 direct entry midwives were required to hold a license to practice in Oregon.

In November 2015, the Health Evidence Review Commission (HERC) approved the final version of the Coverage Guidance: Planned Out-of-Hospital Birth, and Prioritized List Guideline Note 153: Planned Out-of-Hospital Birth; see appendix 2, for location details. The Coverage Guidance includes an extensive evidence review (over 100 pages), conducted over a nearly two year period with extensive public input from stakeholders, and discussed at several public meetings per HERC protocol. The Coverage Guidance is meant for all payers, and is intended as recommendations, not a coverage determination. This Guidance concludes that:

> Planned out-of-hospital (OOH) birth is recommended for coverage for women who do not have high-risk coverage exclusion criteria as outlined below (weak recommendation). This coverage recommendation is based on the performance of appropriate risk assessments and the OOH birth attendant's compliance with the consultation and transfer criteria as outlined below.

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2017-OOHBW-Final-Report
PDF Document · 819 KB

Background: Historical and Policy Context for Direct Entry Midwifery and Out of Hospital Birth in Oregon

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> Planned out-of-hospital (OOH) birth is recommended for coverage for women who do not have high-risk coverage exclusion criteria as outlined below (weak recommendation). This coverage recommendation is based on the performance of appropriate risk assessments and the OOH birth attendant's compliance with the consultation and transfer criteria as outlined below.

Oregon Health Authority

2017 Out of Hospital Births Recommendations

Final Report to Director

> Planned OOH birth is not recommended for coverage for women who have high risk coverage exclusion criteria as outlined below, or when appropriate risk assessments are not performed, or where the attendant does not comply with the consultation and transfer criteria as outlined below (strong recommendation).

Guideline Note 153 consists of the criteria to be used by Oregon Health Plan (Medicaid) to determine whether pregnancies can be considered to be low-risk, as part of the process to prior authorize reimbursement for OOH birth services.

Beginning on January 1, 2015, OHP began a structured prior authorization process for reimbursement of OOH birth services for all licensed provider types practicing within the scope of their licensure. This process requires that the pregnancy meets the HERC criteria for low risk, appropriate and timely documentation is submitted, and that the service is medically appropriate for the member. Oregon Administrative Rules (OARs) define adequate documentation (OARs 410 120 1320, 410 120 1360, 410 130 0200, 410 130 0240, 332 025 0020, 332 025 0021, 332 025 0022, 332 025 0110, 332 025 0120, and medical appropriateness (OAR 410 120 0000). Except in cases where a CCO contracts with a provider of OOH birthing services, members originally enrolled in CCOs are automatically dis-enrolled and re-enrolled in Fee For Service Medicaid (FFS), for the duration of OOH birth services until 60 days post estimated delivery date (EDD). In the case of a CCO contracting with an OOH birth provider, the prior authorization process would be determined by the CCO.

Births in Oregon

During 2015, 46,102 births occurred in Oregon. Of these 2,035 (4.4%) planned an out of hospital birth (home birth or free-standing birthing center). Ultimately, 17% of those planned OOH births occurred in a hospital following transfer of care. As a result, 3.7% of all live births in Oregon in 2015 were delivered outside of the hospital setting.[1] Among births to women who planned out of hospital births, planned birth attendants included: Certified Nurse Midwives (25%), Direct-Entry Midwives (Total 59%, Licensed 52.3%, Unlicensed 6.7%) and Naturopathic

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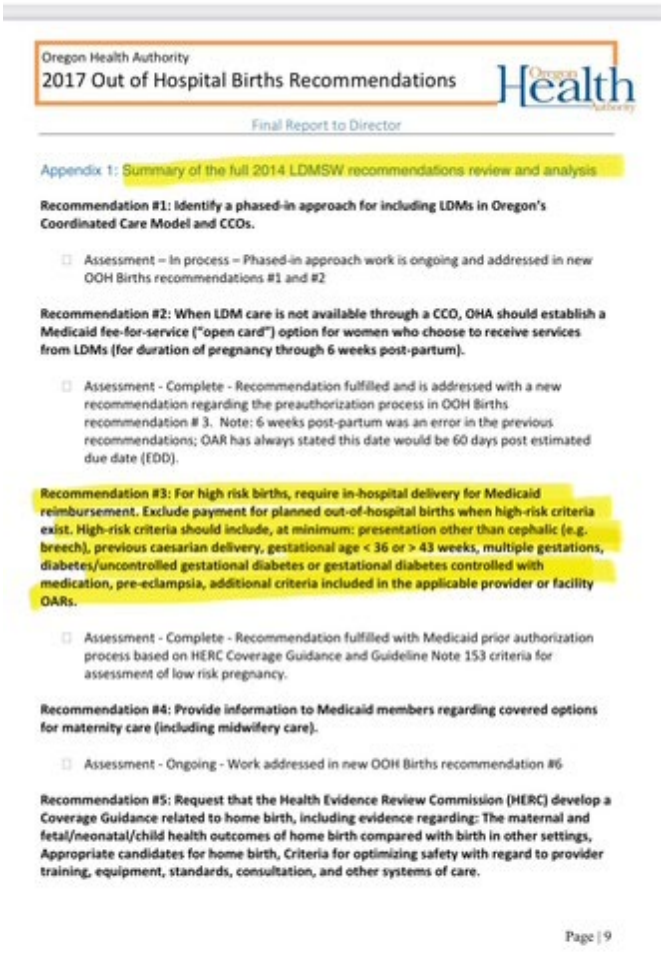

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Appendix 1: Summary of the full 2014 LDMSW recommendations review and analysis

Recommendation #1: Identify a phased-in approach for including LDMs in Oregon's Coordinated Care Model and CCOs.

- Assessment – In process – Phased-in approach work is ongoing and addressed in new OOH Births recommendations #1 and #2

Recommendation #2: When LDM care is not available through a CCO, OHA should establish a Medicaid fee-for-service ("open card") option for women who choose to receive services from LDMs (for duration of pregnancy through 6 weeks post-partum).

- Assessment - Complete - Recommendation fulfilled and is addressed with a new recommendation regarding the preauthorization process in OOH Births recommendation # 3. Note: 6 weeks post-partum was an error in the previous recommendations; OAR has always stated this date would be 60 days post estimated due date (EDD).

Recommendation #3: For high risk births, require in-hospital delivery for Medicaid reimbursement. Exclude payment for planned out-of-hospital births when high-risk criteria exist. High-risk criteria should include, at minimum: presentation other than cephalic (e.g. breech), previous caesarian delivery, gestational age < 36 or > 43 weeks, multiple gestations, diabetes/uncontrolled gestational diabetes or gestational diabetes controlled with medication, pre-eclampsia, additional criteria included in the applicable provider or facility OARs.

- Assessment - Complete - Recommendation fulfilled with Medicaid prior authorization process based on HERC Coverage Guidance and Guideline Note 153 criteria for assessment of low risk pregnancy.

Recommendation #4: Provide information to Medicaid members regarding covered options for maternity care (including midwifery care).

- Assessment - Ongoing - Work addressed in new OOH Births recommendation #6

Recommendation #5: Request that the Health Evidence Review Commission (HERC) develop a Coverage Guidance related to home birth, including evidence regarding: The maternal and fetal/neonatal/child health outcomes of home birth compared with birth in other settings, Appropriate candidates for home birth, Criteria for optimizing safety with regard to provider training, equipment, standards, consultation, and other systems of care.

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- Assessment - Complete - Recommendation fulfilled with HERC adoption of Coverage

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From: Jason Gingerich <JASON.D.GINGERICH@oha.oregon.gov>
Date: January 16, 2025 at 8:44:40 AM PST
To: Sharron Fuchs <[redacted]>, Mautner Dawn <Dawn.Mautner@oha.oregon.gov>
Subject: RE: Is out of hospital VBAC considered a low risk delivery type according to the HERC?

Prior cesarean is a high risk factor according to our guideline so OHP wouldn't cover

out of hospital/community birth after c-section:

https://www.oregon.gov/oha/HPA/DSI-HERC/SearchablePLdocuments//Prioritized-List-GN-153.docx

Let me know if you have further questions or see some inconsistency.
Jason Gingerich
Director, Health Evidence Review Commission
Phone: 503-385-3594

-----Original Message-----
From: Sharron Fuchs <[redacted]>
Sent: Wednesday, January 15, 2025 3:42 PM
To: Jason Gingerich <JASON.D.GINGERICH@oha.oregon.gov>; Mautner Dawn <Dawn.Mautner@oha.oregon.gov>
Subject: Is out of hospital VBAC considered a low risk delivery type according to the HERC?

Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

Hello,

1) Can you please tell me from the extensive investigations into planned out of hospital births by the Oregon Health Evidence Review Commission (HERC), if they determined that Vaginal Birth after C- section (VBAC) is a low risk birth?

2) If indeed out of hospital VBAC is considered by HERC to be low risk , does the Guidance for Planned Out of Hospital Births for Medicaid payment say that Medicaid should / will pay for planned out of hospital VBAC's?

3) Please send me the Medicaid line language and Medicaid line number that indicates that Planned Out of Hospital Births for VBAC is covered by Oregon Medicaid.

Very truly yours,

Sharron Fuchs
Public Citizen

Sent from my iPhone